

TRANSMITTAL OF REPLY BRIEF		Docket No. 22409-00113-US	
In re Application of: Bruce J. Gantz et al.			
Application No. 10/518,811-Conf. #3607	Filing Date July 11, 2005	Examiner E. T. Wu	Group Art 3766
Invention: Cochlear Implant Electrode Array			
<u>TO THE COMMISSIONER OF PATENTS:</u>			
Transmitted herewith is the Reply Brief in this application, with respect to the Examiner's Answer Mailed: <u>September 9, 2008</u> .			
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In the Matter of the

Application of: GANTZ *et al*

Serial No.: 10/518,811

Filed: July 11, 2005

Entitled: COCHLEAR IMPLANT ELECTRODE
ARRAY

Docket No.: 22409-00113-US

Group Art Unit: 3766
Examiner: WU, Eugene Tong

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Commissioner for Patents
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**REPLY BRIEF
UNDER 37 C.F.R. § 41.41**

1. In response to the Examiner's Answer mailed on September 9, 2008, Appellants submit the following reply brief under 37 C.F.R. § 41.41.

I. STATUS OF AMENDMENTS AFTER FINAL

2. Appellants acknowledge the Examiner's indication that the amendments after final rejection filed on January 4, 2008 have not been entered. Appellants notes that the Examiner did not indicate in the Advisory Action mailed January 31, 2008 that the amendments would not be entered, as provided for by the Advisory Action form, but accept the Examiner's present statement that they have and will not be entered.

II. ARGUMENT

3. There are three issues discussed on pages 3-9 of the Examiner's Answer that necessitate an additional response by Appellants regarding the rejections of claims 1-4, 6, 8-10, 12, 13, 22-25, and 36-43 under 35 USC §103(a) as unpatentable over WO00/69513 to

Kuzma in view of U.S. Patent No. 5,143,090 to Dutcher. These issues relate to: (1) the fact that, contrary to the allegations in the Examiner's Answer, the Final Office Action has not identified any substantial evidence to support the Examiner's proposed motivation to combine Kuzma and Dutcher; (2) the fact that the Examiner's proposed combination makes the Kuzma reference unsatisfactory for its intended purpose; and (3) the fact that, contrary to the allegations set out in the Examiner's Answer, the Examiner's proposed combination is based on impermissible hindsight. The arguments presented below are a further clarification to the arguments set forth in Appellants' Appeal Brief.

- A. The Examiner improperly rejected independent claims 1, 22 and 38 and dependent claims 2-3, 6, 8-10, 12, 13, 23-25, 36, 37, 39-43 as being unpatentable over Kuzma in view of Dutcher because there is no suggestion or motivation in the applied art to combine the teachings of Yu '930 and Yu '386.

4. Independent claims 1, 22 and 38 and dependent claims 2-3, 6, 8-10, 12, 13, 23-25, 36, 37, 39-43 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Kuzma in view of Dutcher. Appellants respectfully request that these rejections be reversed for the reasons presented herein.

5. For a rejection under Section 103(a) to be proper it must comply with the statutory provisions and controlling case law. The text of Section 103(a) was stated in the Final Office Action. (*See*, Final Office Action, pg. 2.) The US Supreme Court outlined the four factual inquiries in considering and determining of obviousness under Section 103(a), in *Graham v. John Deere*, as follows:

- (A) Determining the scope and contents of the prior art;
- (B) Ascertaining the differences between the prior art and the claims in issue;
- (C) Resolving the level of ordinary skill in the pertinent art; and
- (D) Evaluating evidence of secondary considerations.

(*See*, 383 U.S. 1, 17-18 (1966).)

6. The MPEP informs that it is Office policy to follow *Graham*. (See, MPEP § 2141.) In determining obviousness, the legal concept of *prima facie* obviousness is a well established procedural tool of examination to allocate the burden between the examiner and applicant. (See, *In re Fielder*, 471 F.2d 640, 642 (CCPA 1973).) Once *prima facie* obviousness is established by the examiner, the burden to rebut the position with objective evidence of no obviousness shifts to the applicant. (See, *Id.* at 642-43.) When a *prima facie* case of obviousness depends on two references there must be some teaching, suggestion or motivation to combine the references. (See, *In re Rouffet*, 149 F.3d 1350, 1357 (Fed. Cir. 1998) (“To prevent the use of hindsight based on the invention to defeat patentability of the invention, this court requires the examiner to show a motivation to combine the references that create the case of obviousness.”).) Substantial evidential support for the motivation to combine the references must be shown in the prior art. (See, *In re Lee*, 277 F.3d 1338, 1343-44 (Fed. Cir. 2002) (“This factual question of motivation is material to patentability, and could not be resolved on subjective belief and unknown authority.”); see also, *In re Kotzab*, 217 F.3d 1365, 1371 (Fed. Cir. 2000) (“[P]articular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed.”).) In the absence of a proper *prima facie* case of obviousness, the applicant is entitled to a patent. (See, *In re Rouffet*, 149 F.3d 1350, 1355 (Fed. Cir. 1998).)

7. For at least the following reasons, Appellants assert that the Examiner has failed to carry this initial burden to establish a *prima facie* case of obviousness based on the existing factual record.

1. The Examiner failed to provide any substantial evidence to support a proper motivation to combine rejection.

8. The Examiner has failed to provide any substantial evidence for the assertion that one

of ordinary skill, without having the benefit of Appellants' novel teachings before them, would have been motivated to combine the teachings of the two references to support the rejection of independent claims 1, 22 and 38 and, as such, has thus failed to establish a *prima facie* case of obviousness. The rejection of independent claims 1, 22 and 38 are therefore improper and should be reversed.

9. In the Answer, the Examiner repeated the assertion from the Final Office Action that Kuzma teaches all limitations of previously presented in independent claims 1, 22 and 38 other than the feature of an "anchor to prevent rotation." (*See*, Examiner's Answer, pgs. 4-6.) The Examiner then alleges that Dutcher can be combined with Kuzma, stating that "Dutcher teaches using a porous polyester fiber mesh... in order to enhance tissue ingrowth to firmly fix the lead to [the] target tissue... Therefore it would have been obvious... to include the mesh of Dutcher with the device of Kuzma, for the purpose of enhancing tissue ingrowth to firmly fix the target tissue. The Office notes that the mesh material in the now modified device of Kuzma serves as an anchor configured to prevent rotation of the carrier along the longitudinal axis of the carrier." (*See*, Examiner's Answer, pg. 4.) The Examiner makes this same argument a total of three time. (*See*, Examiner's Answer, pgs. 5, 6.)

10. In supporting the motivation to combine these two references, the Answer disagrees with Appellants' in that the suggested addition of Dutcher's mesh to the Kuzma device would be a duplication of the benefits provided by the shoulder/tines and flat ("pancake") shaped array of Kuzma. The Examiner provides no objective evidence, but states only that the mesh "enhances" the ability of the now modified Kuzma device to secure the electrode array firmly to [the] target tissue. (*See*, Examiner's Answer, pg. 8, section A.) The Examiner thus points to this "enhanced ability" to "more firmly fix the electrode array to the target tissue than the features of Kuzma alone" as satisfactory motivation for making the suggested combination of

Kuzma and Dutcher. In other words, the Examiner theorizes on the usefulness of adding a mesh to the shoulders of Kuzma, does not provide any motivation for making such a combination, and concludes that a person having ordinary skill would have been motivated to do so because doing so would have been beneficial. Appellants urge that the Examiner has failed to provide substantial evidence to support the combination of Kuzma and Dutcher suggested.

2. The combination of Kuzma with Dutcher, even if proper, would result in a device which would destroy the intended functions of the features in Kuzma

11. In addition to the Examiner's failure to provide a proper motivation to combine Kuzma and Dutcher, the rejections of claims 1, 22 and 38 are also improper because the combination, even if properly motivated, is improper because it would destroy the intended functions of the anti-translation and anti-rotation features of Kuzma. Specifically, in the Answer, the Examiner responds to Appellants' argument by stating that the intended functions of the anti-translation features (tines 16 and shoulder 19) and the anti-rotation features ("pancake" shaped array co-operating with narrow slit in tissue) of Kuzma are not destroyed by adding the mesh of Dutcher to the Kuzma device because "the features of Kuzma cooperate in tandem with the added mesh of Dutcher. There is no loss of functionality." Second, the Examiner states that "*tissue ingrowth takes time... the features of Kuzma perform stabilizing and anchoring functions* up to and including the time when tissue ingrowth on the mesh begins to provide a firm fixation." (See, Examiner's Answer, pg. 8, section B; emphasis added.)

12. Appellants assert that this rationale is improper or incorrect for the following various reasons. First, the Examiner's rationale assumes that the shoulder/tines and flat-shaped array of Kuzma are not wholly sufficient to counteract the translation and/or rotation forces

surround the electrode array of Kuzma at the implantation site. While the Dutcher device is intended to be used in and around the heart, the Kuzma device is said to be used around the cochlea and the other hearing organs. Given the intended location for the Kuzma device, the various other organs, objects and components which may or may not come into contact with the implants of Dutcher and Kuzma, the Examiner has failed to support the implication that those features of Kuzma need enhancing to “more firmly fix” the Kuzma device to the adjacent tissue. The Examiner has also failed to establish that it is even possible to “more firmly fix” the device than what the anti-rotation and anti-translation features of the Kuzma device provide.

13. Secondly, the Examiner’s suggested combination fails to take into consideration the fact that providing temporary “stabilizing and anchoring function [until the] tissue ingrowth on the mesh begins to provide a firm fixation” using the tines/shoulder and flat-shaped array of Kuzma seems to be an overly complicated and incredibly expensive manner of providing temporary fixation. If a temporary fixation or securing is desired, until the ingrowth is sufficient to secure the device to the adjacent tissue, one of ordinary skill would more likely have opted for a simpler and less complex and expensive option, such as for example, adhesives, sutures, staples, among others. More likely, the features of Kuzma are sufficient for the purpose for which they were intended, which is to provide anti-rotation and anti-translation to the Kuzma electrode once it has been implanted in the recipient.

14. Thirdly, the Examiner’s suggestion that the features of Kuzma may be relied on “up to and including the time when tissue ingrowth on the mesh begins to provide a firm fixation” seems to imply that the shoulders/tines and flat-shaped array of Kuzma are not intended to provide long-term anti-rotation and anti-translation benefits to the Kuzma device, and the Examiner appears to be arguing that those features of Kuzma are suitable only short term

anti-rotation and anti-translation features, and that the added Dutcher mesh would provide the long-term anti-rotation and anti-translation benefits to the Kuzma device. This understanding of those features does not appear in Kuzma, and the Examiner provides no support for such an understanding of Kuzma.

15. Finally, regarding short-term and long-term use, one of ordinary skill would appreciate that the performance of the anti-rotation and anti-translation features of Kuzma, both in the short-term (e.g., during implantation or initial activation) as well as long the long-term (e.g., during the operation and use of the Kuzma device in its implanted condition), would further be destroyed by the adding of the Dutcher mesh. Specifically, while the "pancake" shaped array of Kuzma may act to prevent rotation up to a certain amount rotational force, one of skill in the art would appreciate that, given the fact that the "slit" which cooperates with the flat-shaped array is in the recipient's tissue, at some point, the rotational force would cause the array to turn or flip. Similarly, one of ordinary skill in the art would appreciate that although the shoulders and tines of Kuzma would act to keep the Kuzma device from translating because a segment of tissue is held between the shoulder and tines, at some point, the translational force may exceed the ability of the shoulder and tines to hold the array in place and the array would be caused to translate. While this may be detrimental to the implantation or operation of the Kuzma device, on the other hand, such a "flip" or translation may avoid tearing were the device too tightly secured to the tissue. This benefit would not be provided by the combination as suggested by the Examiner, since "ingrowth" of tissue to the added mesh from Dutcher would require that the integrated mesh first tear the tissue to which it is integrated be ripped. While this may be acceptable for certain applications, it certainly would defeat numerous benefits provided by the features of the Kuzma shoulder/tines and flat-shaped array. For at least the reasons above, Appellants assert that the combination of Kuzma with Dutcher, even if proper, would result in a device

which would destroy the intended functions of the features in Kuzma. Therefore, the rejections of independent claims 1, 22 and 38 are *prima facie* improper.

B. The Examiner improperly rejected independent claims 1, 22 and 38, and dependent claims 2-3, 6, 8-10, 12, 13, 23-25, 36, 37, 39-43 as being unpatentable over Kuzma in view of Dutcher Based on Hindsight.

16. The Federal Circuit has repeatedly stated that the use of hindsight must be guarded against by having the Examiner provide substantial evidence to support the motivation. (*See, e.g., In re Rouffet*, 149 F.3d 1350 (Fed. Cir. 1998); *In re Dembiczaik*, 175 F.3d 994 (Fed. Cir. 1999).) There is no objective, substantial evidence on the record of this application that shows a motivation to combine Kuzma in view of Dutcher. Instead, the Examiner claims to find all the elements of Appellants' claimed invention in the two applied references and improperly combines the references without relying on objective evidence. Absent objective evidence, and based on Federal Circuit precedent, it can be reasonably assumed that the Examiner selected the references with the assistance of hindsight. (*See, In re Rouffet*, 149 F.3d 1350, 1358 (Fed. Cir. 1998).) In asserting that the combination is properly motivated, an Examiner may not "use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious." (*See, In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992).) The Federal Circuit has further stated that "[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention." (*See, Id.*) Here, in an attempt to construct a *prima facie* obviousness rejection, the Examiner has selected features from different references, but has not provided substantial objective evidence showing that one of ordinary skill at the time of invention would have combined the same selected elements in the same manner as the Examiner proposes, as explained above. This is impermissible hindsight reconstruction used to reject independent claims 1, 22 and 38.

17. Thus, the only conclusion that can be drawn, based on the record of this application, is that the suggestion forming the basis for the Examiner's otherwise factually unsupported conclusion must have come from Appellants' own novel disclosure; that is, they are based on impermissible hindsight. This failure of the Examiner's reasoning in attempting to make out a *prima facie* obviousness case is sufficient reason alone to reverse the Section 103 rejection of independent claims 1, 22 and 38, and dependent claims 2-3, 6, 8-10, 12, 13, 23-25, 36, 37, 39-43.

II. CONCLUSIONS

18. For the reasons noted above as well as the reasons provided in the Appeal Brief filed on June 4, 2008, Appellants submit that the pending claims define patentable subject matter. Accordingly, Appellants request that the Examiner's rejection of these claims be reversed and that the pending application be passed to issue.

Respectfully submitted,

Dated: November 10, 2008

Respectfully submitted,

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